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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,125	01/09/2001	Tadamitsu Kishimoto	053466/0296	6506

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EXAMINER	
EWOLDT, GERALD R	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
08/11/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/756,125	KISHIMOTO ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,13 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,13 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/27/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's IDS filed 4/27/09 and amendment and remarks filed 5/20/09 have been entered.

2. Claims 9, 13, and 14 are being acted upon.

3. The specification stands objected to for the following reasons. The attempt to incorporate subject matter into this application by reference to WO 92/19759 remains improper. Applicant has attempted to amend the specification to add the amino acid sequences of reshaped hPM-1 V_H version "f" and V_L version "a" (SEQ ID NOs:56 and 57 in WO 92/19759). Applicant has further improperly amended the Sequence Listing to include both these amino acid sequences (SEQ ID NOS:18 and 20 in the instant application), as well as adding nucleic acid sequences (SEQ ID NOs:17 and 19 in the instant application).

A review of the Tables in the translation of WO 92/19759 reveal the hPM-1 H and L chain V regions (on top), and several reshaped versions of the V regions. The instant specifications simply states that, "a preferred example of such a reshaped human antibody is hPM-1 (see Unexamined Patent Application No. WO 92-19759)." Accordingly, the only teaching that can be reasonably incorporated from Unexamined Patent Application No. WO 92-19759 is an antibody comprising the complete disclosed V_H and V_L regions of hPM-1, i.e., the first (top) sequences in Tables 2 and 3 and not reshaped versions of these sequences. Additionally, the amino acid sequences of these hPM-1 V_H and V_L can be encoded by numerous nucleic acid sequences any or all of which would comprise new matter in the instant application because the instant application does not refer or incorporate by reference nucleic acid sequences which encode the hPM-1 antibody.

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 9, 13, and 14 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a rejection for the introduction of new matter into the claims.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically: a method employing the hPM-1 antibody comprising reshaped hPM-1 V_H version "f" and V_L version "a" (SEQ ID NOs:56 and 57 in WO 92/19759, SEQ ID NOs:18 and 20 in the instant application).

Applicant is advised that, as the amendment to the specification is improper, as set forth in Section 3 above, the new claims are also improper and thus, comprise the introduction of new matter into a claims. Further, the antibody of Sato et al. (1993) has not been incorporated by reference in the instant application as stated in Applicant's remarks. Indeed, there are no incorporations by reference in the instant application.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 9, 13, and 14 stand rejected under the judicially created doctrine of obviousness-type double patenting as being

unpatentable over Claims 1, 9, and 10 of U.S. Patent Application No. 11/585,172. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claim and the claims of the '172 application both recite the a method of treating an IL-6 mediated disease, which would encompass chronic rheumatoid arthritis, by administering to a patient in need a PM-1 antibody, in particular the monoclonal hPM-1 antibody of FERM BP 2998 (which comprises the CDRs of the instant claims). Note that the method of inhibiting synovial cell growth of instant Claim 9 is clearly a treatment for arthritis.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant requests that this rejection be held in abeyance.

Applicant is advised that should this be the only remaining rejection after Final rejection the filing of a terminal disclaimed to overcome the rejection may be considered to be a new issue after Final rejection.

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from

7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara, Ph.D. can be reached on (571) 272-0878.

11. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

/G.R. Ewoldt/
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